PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PG4657-2/PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/00599	International filing date *(day/month/year)* 22.01.2003	Priority date *(day/month/year)* 25.01.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.08.2003	13.01.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/00599

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-60 as originally filed

Claims, Numbers

1-37 as originally filed

Drawings, Sheets

1/16-16/16 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 37

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 37

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-30, 33
	No:	Claims	1, 31, 32, 34-36
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	2-30, 33
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	-

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 37 was not searched in view of Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT and therefore no substantive examination can be performed.
Moreover, claim 37 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with on the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject-matter of claim1 is not new.

The document WO-A-0139823 discloses (the references in parentheses applying to this document):

a medicament dispenser (13) for use in the delivery of a combination medicament product, the dispenser (13) comprising:
a first medicament container (14) for containing a first medicament active component (16);
a first release means (20) for releasing a dose portion of said first medicament active component (16) from said first medicament container (14);
a second medicament container (15) for containing a second medicament active component (17); and
a second release means (21) for releasing a dose portion of said second medicament active component (17) from said second medicament container (15),
wherein the first medicament active component (14) is kept separate from the second medicament active component (15) until the point of release thereof for delivery in combination, and wherein the first medicament active component (14) is selected from the group consisting of salmeterol, formoterol and any salts or

solvates thereof (bronchodilators) and the second medicament active component (15) is selected from the group consisting of beclomethasone ester, fluticasone ester and any salts or solvates thereof (anti-inflammatory agents).

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

The above novelty objection also holds true in view of documents WO-A-0064519 (page 3, line 21 to page 6, line 2), US-A1-2001027789 (page 4. left-hand column, lines 19 to 40), WO-A-0204055 (page 3, line 15 to page 5, line 15), US-A-5002048 (column 2, line 6 to column 3, line 14).

The device disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met.

Dependent claims 2-36 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT, the reasons being as follows:

claims 2 - 6:

the combination of medicaments disclosed in these dependent claims is disclosed in the list of "bronchodilators" and "anti-inflammatory agents" given in e.g. documents WO-A-0139823, WO-A-0064519 and US-A1-2001/027789. A combination of specific medicaments of these groups can only be regarded as inventive (Article 33(3) PCT), if the combination of medicaments presents unexpected effects or properties in relation to the rest of the range. However, no such effects or properties are indicated in the application. Hence, no inventive step is present in the subject-matter of claims 2 - 6,

claims 7-9 and 14-18:

these claims do not involve an inventive step (Article 33(3) PCT), as unit dose container packs are known in the prior art. Both capsules and blisters are known to be arranged on carriers that are either disc-shaped or shaped as elongated strips, see also GB-A-1387954 (page 1, left-hand column, line 32 to page 1, right-hand column, line 74) and WO-A-9834664 (page 1, line 20 to page 4, line 5 and page 9, line 23 to page 10, line 6),

claims 10 and 19:

the filling of a particular type of carrier by means of either printing, painting or vacuum occluding is known from document. See WO-A-0045879 (page 4, lines 12 to 15). It is therefore considered that the subject-matter of these claims does not involve an inventive step (Article 33(3) PCT),

claims 11-13:

these claims do not involve an inventive step (Article 33(3) PCT), as reservoir container packs with metering means are known in the prior art, see also US-A1-2001/027789.

claims 20-30:

these claims relate to the composition of the administered medicament. Components of the medicament formulation can not be considered to involve an inventive step (Article 33(3) PCT), as they are well known to the person skilled in the art. See WO-A-0198176 (page 1, line 13 to page 2, line 23 and page 7, line 6 to page 9, line 8)

claim 31:

the subject-matter of this claim is not new (Article 33(2) PCT). Documents WO-A-0139823 (figure 7), WO-A-0064519 (figure 1) of the search report show, in combination with the subject-matter of claim 1, the first and second release means to be coupled,

claims 32 and 33:

the shape and size of the medicament containers can not be considered to involve an inventive step (Article 33(3) PCT). Eventhough documents in the prior art appear to contain only doses of the same size, it comes within the knowledge fo the skilled person to administer equivalent or non-equivalent dose portions as the situation occurs. Modification of the composition of the size and/or shape of the containers is merely an alternative solution to the problem of correctly dosing the medicament,

claims 34-36:

refilling a medicament container is known in the prior art WO-A-0204055 (page 3, line 14 to page 5, line 15). This document also discloses refill cassettes for the

medicament containers, both as separate refills or as a single refill. The subject-matter of these claims is therefore not new (Article 33(2) PCT).

Claims 2 to 36 depend from claim 1 and refer to further embodiments of the medicament dispenser described in claim 1 and thus meet the requirements of Article 33(4) PCT for the same reasons explained above.